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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,540	07/09/2003	Sai Kiang Lim	4810-66314	8220

7590 10/16/2006

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,540	LIM, SAI KIANG	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) *5-11 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 8/8/06 to claims 1-6 and 13-17 have been entered. Claims 18 and 19 have been cancelled. Claims 1-11 and 13-17 remain pending in the current application, of which claims 1-4 ONLY are being considered on their merits. Prior art references not included with this Office action can be found in a prior action. In the future, applicant should note that claims that are both withdrawn and currently amended (as are claims 5-7 and 13-17) should be denoted "withdrawn – currently amended," not "amended and withdrawn," in accordance with 37 C.F.R. 1.121(c)(2) in order to avoid receiving a notice of noncompliant amendment. Prior art references not included with this Office action can be found in a prior action.

Double Patenting

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/521071.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of instant claim 18 is completely encompassed by the scope of claims 1-3 of the '071 application. Instant claim 18 requires that the cells of claim 1, which are identical to the cells of claim 1 of the '071 application as claimed, be from a single clone. Because the '071 claims do not limit the source of cells, they therefore encompass cells obtained from any source that meet all the limitations of said claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection will be withdrawn if claims 1-4 are otherwise found allowable or a terminal disclaimer is filed over the '071 application.

Claim Rejections - 35 USC § 112

The rejections of claims 1-4 under 35 U.S.C. § 112, first and second paragraphs, are withdrawn in light of applicant's comments and the claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejections of claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by Hughes et al. in light of Rafii et al. and Kraus et al. (WO 00/11139); under 35 U.S.C. § 102(e) as being anticipated by Kraus et al. (U.S. Patent 6,429,012); and under 35 U.S.C. § 102(a) as being anticipated by Miyajima et al. are withdrawn in light of the amendments to the claims and applicant's comments. The rejection of claims 2 and 4 under 35 U.S.C. § 102(e) as being anticipated by Scott et al. is withdrawn in light of the claim amendments.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(e) as being anticipated by Scott et al. (2003, U.S. Patent Application Publication 2003/0180265). The claims are drawn to a monoclonal cell line that gives rise to both hematopoietic and endothelial lineages, said composition comprising cells that have all four properties as recited in claim 1. In some dependent claims, the cells do not react with any of the seven recited markers. In some dependent claims, the cells are human.

Scott et al. teach a clonal cell population that can make both blood (hematopoietic tissue) and blood vessels (endothelial tissue) (paragraph 0065). The cells of Scott et al. may be isolated from mice (paragraph 0058) or from any other mammal, including humans (paragraph 0025). Scott et al. teach injecting a single cell from their isolated population into a mouse (paragraph 0065), where it expands and self-renews, providing blood and blood vessels (paragraph 0064).

Whether the purified population of Scott et al. was known before the instant invention to possess all four properties recited in claim 1 is immaterial on its own to the patentability of the composition of Scott et al. Something that is old does not become patentable upon the discovery of a new property, use, or application. That is, even if applicant had discovered new properties (*i.e.*, the ability to proliferate in an *in vitro* culture for more than 40 generations; the inability to induce tumor formation in an immunodeficient Rag-1 mouse; and the inhibition from differentiation when cultured on a gelatinized, feeder-free layer) of the cells of Scott et al., the cells *per se* would not be patentable.

In the instant case, the ability to proliferate in an *in vitro* culture for more than 40 generations; the inability to induce tumor formation in an immunodeficient Rag-1 mouse; and the inhibition from differentiation when cultured on a gelatinized, feeder-free layer all flow from the fact that the instantly claimed cells, like the cells described by Scott et al., differentiate to both hematopoietic and endothelial lineages (paragraph 0065).

Applicant alleges that Scott et al. do not describe culturing a single clone to establish a cell line (Reply, page 13, paragraph 2). Applicant also refers to the now-withdrawn rejections under 35 U.S.C. § 112, first paragraph (Reply, page 13, paragraph 5, through page 14, paragraph 2).These arguments have been fully considered, but they are not persuasive.

Scott et al. teach transplanting a single cell from their composition into immunodeficient mice (paragraph 0065); Scott et al. further teach that cells so transplanted "expand and self-renew" and to reconstitute the hematopoietic system of the irradiated host (paragraph 0064). According to the MedlinePlus Merriam-Webster Online Medical Dictionary (http://www.nlm.nih.gov/medlineplus/mplusdictionary.html; reference U), a "cell line" is "a cell culture selected for uniformity from a cell population derived from a usually homogeneous tissue source," while a "tissue [or cell] culture]" is "the process of making body tissue grow in a culture medium outside the organism." By this definition, the single cell transplanted into a different animal by Scott et al. is being "cultured." The cell "expands and self-renews," thus creating a monoclonal population of cells within the host organism.

Applicant's comments regarding enablement and written description are noted, but they are moot, since applicant's arguments have overcome the 35 U.S.C. § 112, first paragraph, rejections of record.

This rejection over Scott et al. would be overcome if the limitations of claim 2 were incorporated into claim 1; by a substantive evidentiary showing that the cells of Scott et al. do not possess at least one of the properties recited in claim 1; or by any of the showings directed by M.P.E.P. § 2136.05.

Claims 1-4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Furcht et al. (2004, U.S. Patent Application Publication 2004/0107453). The claims are drawn to a composition comprising mammalian cells that give rise to both hematopoietic and endothelial lineages, said composition comprising cells that have at least one of four properties as recited in claim 1. In some dependent claims, the cells do not react with at least one of seven recited markers. In some dependent claims, the cells are human. In some dependent claims, the cells are from a single clone.

Furcht et al. teach human multipotent adult stem cells (MASC), which are obtained from human bone marrow and do not express CD31, CD34, Tie, or CD62/P-selectin (Example 3; paragraphs 0110-0112). The MASCs of Furcht et al. can give rise to cells of multiple lineages, including hematopoietic cells (paragraphs 0029 and 0030; Example 7; paragraphs 166-168) and endothelial cells (paragraphs 0029 and 0030; Example 9; paragraphs 0126-0130; Figures 5-7). The MASCs of Furcht et al. do not cause teratomas when implanted into a recipient mammal (paragraph 0044).

Whether the purified population of Furcht et al. was known before the instant invention to possess all four properties recited in claim 1 is immaterial on its own to the patentability of the composition of Furcht et al. Something that is old does not become patentable upon the discovery of a new property, use, or application. That is, even if applicant had discovered new properties (*i.e.*, the ability to proliferate in an *in vitro* culture for more than 40 generations; the inability to induce tumor formation in an immunodeficient Rag-1 mouse; and the inhibition from differentiation when cultured on a gelatinized, feeder-free layer) of the cells of Furcht et al., the cells *per se* would not be patentable.

In the instant case, the ability to proliferate in an *in vitro* culture for more than 40 generations; the inability to induce tumor formation in an immunodeficient Rag-1 mouse; and the inhibition from differentiation when cultured on a gelatinized, feeder-free layer all flow from the fact that the instantly claimed cells, like the cells described by Furcht et al., differentiate to both hematopoietic and endothelial lineages (Examples 7 and 9, *inter alia*) and do not cause tumors when implanted into recipients (paragraph 0044).

Applicant alleges that Furcht et al. do not teach a monoclonal cell line (Reply, page 14, paragraph 7). This argument has been fully considered, but it is not persuasive. At paragraphs 0136-0139, Furcht et al. detail an experiment in which MASCs are transduced with a retroviral vector (paragraph 0137) and expanded into a "clonal" population (paragraph 0138, lines 3-5). Furcht et al. specifically characterize this experiment as demonstrating that "MASC are indeed 'clonal' multipotent cells" (paragraph 0137, lines 2-3).

This rejection would be overcome by a substantive evidentiary showing that the cells of Furcht et al. do not possess at least one of the properties recited in claim 1; by a substantive evidentiary showing that the cells of Furcht et al. react with at least one of the markers recited in claim 2; or by any of the showings directed by M.P.E.P. § 2136.05.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

SANDRA E. SAUCIER
PRIMARY EXAMINER